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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/853,292	05/09/97	TOVEY	M 23164-1003

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1646	15

DATE MAILED: 10/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/853,292	TOVEY
Examiner	**Group Art Unit**
David L. FITZGERALD	1646

☒ Responsive to communication(s) filed on *13 August 1999 (CPA + amendment)*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *THREE (3)* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-5 and 7-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5 and 7-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. The receipt of a request filed on 13 August under 37 C.F.R. § 1.53(d) for a Continued Prosecution Application (CPA) based on parent application serial no. 08/853,292 is acknowledged.

In order for the request to be proper, an extension of time in the parent application is necessary to establish copendency of the original and continuing applications. Counsel's authorization to charge "any additional fees which may be required" will be construed as a petition for the necessary extension of time and an authorization to charge the requisite fee. *See* M.P.E.P. § 201.06(d). Accordingly, counsel's **deposit account no. 08-1641 will be charged $110 for one month's extension** of the period for response to the final rejection mailed 13 April 1999, from 13 July to 13 August 1999.

In view of the extension of time, the request for filing of a CPA is acceptable. A CPA has been established, and an action on the CPA follows.

2. Insofar as the rejections of record are maintained below, applicant's arguments filed 13 August 1999 have been fully considered, but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to claims 13 and 14 under 37 C.F.R. § 1.75(b) as being duplicative is maintained for the reasons stated at ¶ 2 of Paper No. 5 and reiterated at ¶ 2 of Paper No. 9.

Applicant advances the same argument made in the reply under 37 C.F.R. § 1.116 on 18 June 1999 (Paper No. 11) and fully addressed in the subsequent advisory action (Paper No. 12). The argument remains unpersuasive for the reasons previously stated.

4. Claim 2 remains rejected under 35 U.S.C. § 102(b) as anticipated by Cummins '382 for the reasons discussed at ¶ 4 of Paper No. 5 and ¶ 3 of Paper No. 9.

Applicant states that the methods exemplified by the reference provide at most cumulative doses of 140 IU of IFN-α for the treatment of a viral disease. Claim 2 is not limited to the treatment of viral diseases, and as explained previously, Cummins exemplifies protocols which involve the cumulative administration of *ca.* 4200 IU of IFN. *See* '382 at col. 12, lines 14-35 and the examiner's analysis at ¶ 4 of Paper No. 5. Applicant's observations are not demonstrative of error in the examiner's analysis.

Applicant further urges that Cummins cannot anticipate claim 2 because it does not describe doses from 21.4 IU/kg to 2.9 x 10^4 IU/kg. This argument is not persuasive because claim 2 does not recite the dosage range which applicant urges.

Applicant's amendments have obviated the present rejection with respect to claim 1 and the claims dependent therefrom.

5. The rejection of claims 1-5, 7, 8, 10-12, and 15-18 under 35 U.S.C. § 102(b) as anticipated by Samo *et al.* (*J. Infect. Dis.*, 1984) is maintained for the reasons stated at ¶ 5 of Paper No. 5 and reiterated at ¶ 4 of Paper No. 9.

Applicant argues that the claims require the treatment of an "existing viral infection" and that Samo fails to teach this limitation. This argument is not persuasive because the claims recite nothing relative to the existence of any extant infection, and applicant has not explained why a prophylactic treatment as described in the prior art is not a "method for treating" within the meaning of claim 2 and the claims which depend from it. It is also noted that claim 1 and its dependent claims require only the stimulation of "systemic host defense mechanisms" without reference to the nature or existence of any condition which might be ameliorated by the stimulation.

It is also urged that the disease treated in the prior art is not a "systemic viral condition." This argument is not persuasive because as the prior art evidences, rhinovirus infection is associated with a variety of systemic effects. *See* Samo at 182, col. 2 (*e.g.*, "[a] volunteer was defined as ill if he or she had respiratory and/or systemic symptoms"). Furthermore, as noted above, claim 1 and the claims which depend from it recite no limitation regarding the nature or existence of any condition which might be ameliorated by the required stimulation.

Lastly, applicant argues that intranasal administration, as described by the reference, does not meet the limitation of providing oromucosal contact. As explained previously, "oromucosal" administration as employed in the present disclosure reasonably appears to comprehend conventional intranasal administration. *See* Paper No. 9, page 3, lines 1-8. Applicant has offered neither argument nor evidence to rebut the examiner's position on this point.

The composition claims have not been amended, and applicant has advanced no argument to explain why the prior art compositions do not meet their limitations.

6. Claims 1-3, 5, 7, 8, 13, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Iida (*Vaccine*, 1989) for the reasons elaborated at ¶ 4 of Paper No. 5.

Applicant urges that Iida does not anticipate the present claims because it does not teach that the administered IFN has therapeutic effects removed from the application site. This observation is in error: the various viral agents against which IFN-γ was shown to be efficacious were administered intravenously, whereas the IFN was provided by an intranasal route. It is, furthermore, irrelevant because the method as described in the prior art will inherently produce systemic effects whether the reference describes them or not.

It is also argued that the reference does not anticipate claim 2 because it fails to show any benefit of IFN administered post-infection. This argument is not persuasive because, as discussed above, claim 2 is reasonably construed to comprehend the prophylactic therapies exemplified in the prior art.

7. The rejection of claim 9 under 35 U.S.C. § 103 as being unpatentable over Iida (*Vaccine*, 1989) for the reasons stated at ¶ 8 of Paper No. 5 and repeated at ¶ 6 of Paper No. 9.

Applicant first argues that Iida does not teach oromucosal administration of an IFN; that it does not describe the claimed dosages; and that it does not describe treatment "for the systemic stimulation of host defense mechanism." These arguments are not persuasive for the reasons discussed previously and above with respect to other references. As noted, oromucosal administration as instantly claimed reasonably appears to comprehend intranasal administration. As explicated in the original statement of the rejection, the dosages described in the prior art (10^1 to 10^3 IU of IFN-γ) appear to fall within the recited dosage range given that the recipients were mice (which typically weigh on the order of 25 to 50 g). The reference plainly describes systemic efficacy of the IFN with respect to a variety of viral challenges, and one of ordinary skill in the art would have gleaned as much from a reading of the reference.

It is applicant's position that *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A., 1980), is not on-point with respect to this rejection because "the use of interferon in the present invention is not for the same purpose as Iida." The examiner does not understand this assertion. The prophylactic therapies described in the prior art reasonably appear to fall within the scope of "a method for stimulating systemic host defense mechanisms in a mammal" as required by the instant claim.

Applicant protests that Iida provides no motivation to administer IFN-γ and another cytokine concurrently, concluding that the rejection must be based upon improper hindsight and that the reference does not convey a reasonable expectation of success in the practice of a method as now claimed. This line of argument is not persuasive. Motivation subsists in the description in the prior art of the efficacious use of two agents independently for the same purpose, wherein that purpose comports with that now claimed. *In re Kerkhoven*, *id.* The artisan would reasonably have expected that a combination of the two agents for prophylaxis against the same infectious agent would be efficacious because each of the two agents is disclosed to be efficacious when used singly. *See id.*

8. Claims 1-5 and 7-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cummins '382 in view of either of Samo (*J. Infect. Dis.*, 1984) or Iida (*Vaccine*, 1989) for the reasons stated at ¶ 9 of Paper No. 5 and at ¶ 7 of Paper No. 9.

New claims 19-21 do not patentably distinguish over the prior art because, in view of the teachings in the prior art that IFNs may be efficaciously employed to treat any viral infection and the well-documented antiviral activity characteristic of all IFNs, the artisan would reasonably have expected that the methods suggested by the prior art would have been useful to treat infection by any known viral agent.

Applicant argues that the prior art does not suggest the dosage ranges now claimed. This argument remains unpersuasive. "[T]he test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art *presumed* to be familiar with them." *In re Rosselet,* 52 CCPA 1533, __, 146 USPQ 183, 186 (CCPA 1965); emphasis in original; *accord*, *In re Oetiker* (Nies, C.J., concurring), 977 F.2d 1443, __, 24 USPQ2d 1443, 1446-47 (Fed. Cir. 1992). As discussed previously on this record, the prior art fairly provides motivation to use doses higher than those exemplified by Cummins but lower than those exemplified by Samo and Iida because all of the prior art dosages were known to be effective for the treatment of viral infection. The artisan would reasonably have expected that any intermediate dosage range would likewise be effective.

It is urged that Cummins teaches away from using any higher dose than it exemplifies because in one experiment (out of five involving treatment of canine herpesvirus infection and

amid the exemplification of the treatment of roughly a dozen diseases in four mammalian species), a suboptimal result was observed with a relatively higher IFN dose. Here applicant mistakes the description of a beneficial but suboptimal result for a teaching that no benefit will result from the use of a higher dose. Applicant's argument is not persuasive because *all* of the references, considered *collectively* for all that they fairly teach to one having ordinary skill in the art, reasonably suggest that therapeutic benefit would be afforded by the use of doses higher than those exemplified by Cummins in the treatment of a range of viral diseases.

The examiner agrees that toxicity was a known undesirable side effect of high-dose IFN therapy at the time of the invention, and the Samo reference may fairly be read to teach away from employing dosages higher than those exemplified by Samo. Neither of these considerations, however, teaches away from using a lower dosage (*i.e.*, a dose intermediate between the Cummins dosages and the "conventional" dosages) because the artisan would have expected toxicity to be decreased, relative to the dosages described by Samo and Iida, with the use of a lower dose.

Lastly, applicant reiterates the assertion that none of the references teaches oromucosal administration of IFN or "systemic" effects. These arguments are not persuasive for the reasons discussed above and previously with respect to the references individually.

9. The examiner believes that he has addressed all pertinent arguments. No claim is allowed.

10. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone	(703) 308-3934
Fax	
All formal papers	(703) 308-4242
Informal communications	(703) 308-0294
e-mail (note PTO policies below)	david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1600 receptionists at (703) 308-0196.

DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

19 October 1999

The **best time to reach Examiner Fitzgerald** is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the acting supervisor for this Art Unit, Paula Hutzell, may be reached at (703) 308-4310.

Most official papers and all informal **communications may be submitted to the PTO by fax.** For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

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